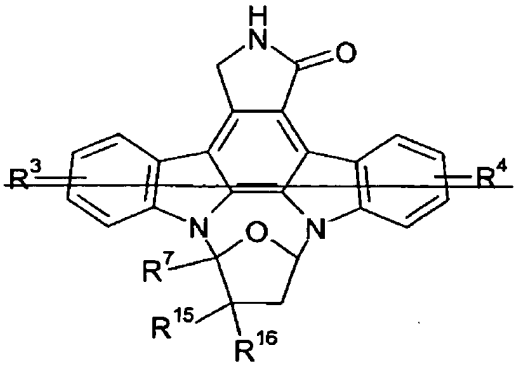
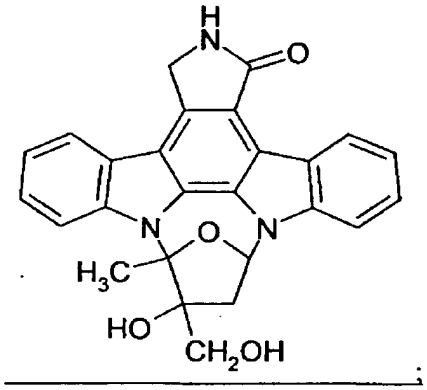
DOCKET NO.: CP185B
APPLICATION NO.: 10/718,077
OFFICE ACTION DATED: AUGUST 9, 2007

LISTING OF THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A composition comprising a fused pyrrolocarbazole with the formula:





~~wherein~~

~~R^3 and R^4 are selected from H, alkyl, Cl, Br, CH_2OH, $CH_2SOCH_2CH_3$, $CH_2SO_2CH_2CH_3$, $NHCONHC_6H_5$, $CH_2SCH_2CH_3$, $CH_2SC_6H_5$, $NHCO_2CH_3$, $CH_2OC(=O)NHCH_2CH_3$, $N(CH_3)_2$, $CH=NNH$, $CH_2N(CH_3)_2$, and $CH_2OCH_2CH_3$; R^7 is selected from H and alkyl; and R^{15} and R^{16} are independently selected from H, alkyl,~~

~~OH, CH_2OH, alkoxy, and CO_2alkyl; or a stereoisomer or pharmaceutically acceptable salt form thereof;~~ at least 20% (w/w) of a poloxyl stearate; and at least one polyethylene glycol.

2. (Original) The composition of claim 1 wherein the fused pyrrolocarbazole is present at a concentration of about 1 to about 100 mg/mL.

3. (Original) The composition of claim 2 wherein the fused pyrrolocarbazole is present at a concentration of about 1 to about 50 mg/mL.

4. (Canceled)

5. (Canceled)

6. (Original) The composition of claim 1 wherein the polyethylene glycol has a molecular weight from about 300 to 8000 Daltons.

7. (Original) The composition of claim 6 wherein the polyethylene glycol has a molecular weight from about 400 to 3350 Daltons.

8. (Original) The composition of claim 7 wherein the polyethylene glycol has a molecular weight from about 400 to 1500 Daltons.

9. (Currently Amended) The composition of claim ~~5~~ 1 wherein the polyethylene glycol is selected from PEG-400, PEG-600, PEG-1000, and PEG-1450.

10. (Original) The composition of claim 9 wherein the polyoxyl stearate is Myrj® 52.

11. (Original) The composition of claim 10 wherein the ratio of polyethylene glycol:polyoxyl stearate ranges from 50:50 to 80:20.

12. (Original) The composition of claim 11 wherein the ratio of polyethylene glycol:polyoxyl stearate is 50:50.

13. (Original) The composition of claim 11 wherein the ratio of polyethylene glycol:polyoxyl stearate is 80:20.

14. (Original) The composition of claim 1 comprising a polyethylene glycol mixture selected from PEG-400/PEG-1000, PEG-400/PEG-1450, PEG-600/PEG-1000, and PEG-600/PEG-1450.

15. (Original) The composition of claim 14 wherein the ratio of the polyethylene glycol mixture:polyoxyl stearate is from 50:50 to 80:20.

16. (Original) The composition of claim 15 wherein the ratio of the polyethylene glycol mixture:polyoxyl stearate is 50:50.

17. (Original) The composition of claim 15 wherein the ratio of the polyethylene glycol mixture:polyoxyl stearate is 80:20.

18. (Original) The composition of claim 16 wherein the composition comprises PEG-400:PEG-1000:polyoxyl stearate in a ratio of 25:25:50.

19. (Original) The composition of claim 16 wherein the composition comprises PEG-400:PEG-1450:polyoxyl stearate in a ratio of 25:25:50.

20. (Original) The composition of claim 17 wherein the composition comprises PEG-400:PEG-1000:polyoxyl stearate in a ratio of 40:40:20.

21. (Original) The composition of claim 17 wherein the composition comprises PEG-400:PEG-1450:polyoxyl stearate in a ratio of 40:40:20.

22. (Withdrawn) A method of treating a disease or disorder in a mammal, comprising administering a composition of claims 1, 12, or 19 to a subject in need thereof.

23. (Withdrawn) The method of claim 22 wherein the disorder is a neurological disorder.

24. (Withdrawn) The method of claim 22 wherein the disorder is cancer.

25. (Withdrawn) The method of claim 24 wherein the cancer is prostate cancer.

26. (Withdrawn) The method of claim 24 wherein the cancer is acute myelogenous leukemia.

27. (Withdrawn) A method for preparing a composition of comprising a fused pyrrolocarbazole, at least one organic solvent, at least one surfactant, and optionally an antioxidant wherein the composition is non-aqueous and particle-forming comprising:

(a) heating the organic solvent and optionally the antioxidant to about 50-90 °C to form a heated mixture;

(b) mixing the fused pyrrolocarbazole in the heated mixture with a high shear homogenizer to form a homogenized mixture; and

(c) mixing the surfactant to the homogenized mixture.

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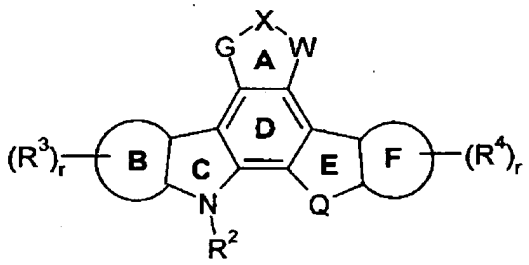
28. (Withdrawn) The method of claim 27 wherein the composition includes at least one antioxidant.

29. (Withdrawn) The method of claim 27 wherein the temperature is from about 50-80 °C.

30. (Withdrawn) The method of claim 29 wherein the temperature is from about 50-70 °C.

31. (Withdrawn) The method of claim 27 wherein the fused pyrrolocarbazole has the formula:



or a stereoisomer or pharmaceutically acceptable salt form thereof, wherein:

ring B and ring F, are independently selected from:

a) an unsaturated 6-membered carbocyclic aromatic ring in which from 1 to 3 carbon atoms may be replaced by nitrogen atoms;

b) an unsaturated 5-membered carbocyclic aromatic ring; and

c) an unsaturated 5-membered carbocyclic aromatic ring in which either:

1) one carbon atom is replaced with an oxygen, nitrogen, or sulfur;

2) two carbon atoms are replaced with a sulfur and a nitrogen, an oxygen and a nitrogen, or two nitrogens; or

3) three carbon atoms are replaced with three nitrogens;

G-X-W is selected from:

a) $-(Z^1Z^2)C-N(R^1)-C(Z^1Z^2)-$;

b) $-CH(R^1)-C(=O)-N(R^1)-$; and

c) $-N(R^1)-C(=O)-CH(R^1)-$;

Z^1 and Z^2, at each occurrence, are independently selected from H, H; H, OR; H, SR; H, $N(R)_2$; and a group wherein Z^1 and Z^2 together form a moiety selected from =O, =S, and =NR; with the proviso that at least one of the pairs Z^1 and Z^2 form =O;

R is selected from H, substituted or unsubstituted alkyl having from 1 to 6 carbons, OH, alkoxy having from 1 to 4 carbons, $OC(=O)R^{1a}$, $OC(=O)NR^{1c}R^{1d}$, $O(CH_2)_pNR^{1c}R^{1d}$, $O(CH_2)_pOR^{1b}$, substituted or unsubstituted arylalkyl having from 6 to 10 carbons, and substituted or unsubstituted heteroarylalkyl;

R^1 is selected independently from:

a) H, substituted or unsubstituted alkyl having from 1 to 6 carbons, substituted or unsubstituted aryl, substituted or unsubstituted arylalkyl, substituted or unsubstituted heteroaryl, and substituted or unsubstituted heteroarylalkyl;

b) $C(=O)R^{1a}$;

c) OR^{1b};

d) $C(=O)NHR^{1b}$, $NR^{1c}R^{1d}$, $(CH_2)_pNR^{1c}R^{1d}$, $(CH_2)_pOR^{1b}$, $O(CH_2)_pOR^{1b}$ and $O(CH_2)_pNR^{1c}R^{1d}$;

R^{1a} is selected from substituted or unsubstituted alkyl, substituted or unsubstituted aryl and heteroaryl;

R^{1b} is selected from H and substituted or unsubstituted alkyl having from 1 to 6 carbons;

R^{1c} and R^{1d} are each independently selected from H, substituted or unsubstituted alkyl having from 1 to 4 carbons, and a linking group of the formula $-(CH_2)_2-X^1-(CH_2)_2-$;

X^1 is selected from -O-, -S-, and $-CH_2-$;

R^2 is selected from H, SO_2R^{2a}, CO_2R^{2a}, $C(=O)R^{2a}$, $C(=O)NR^{2c}R^{2d}$,

and alkyl of 1-8 carbons, alkenyl of 2-8 carbons, alkynyl of 2-8 carbons, wherein:

1) each alkyl, alkenyl, and alkynyl is unsubstituted; or

2) each alkyl, alkenyl, and alkynyl is substituted with 1-3 R^5;

R^{2a} is selected from alkyl of 1 to 6 carbons, aryl, OR^{2b},

$CONH_2$, $NR^{2c}R^{2d}$, $(CH_2)_pNR^{2c}R^{2d}$, and $O(CH_2)_pNR^{2c}R^{2d}$;

R^{2b} is selected from H and substituted or unsubstituted alkyl

having from 1 to 6 carbons;

R^{2c} and R^{2d} are each independently selected from H,

substituted or unsubstituted alkyl having from 1 to 6 carbons, and a linking group of the formula

$-(CH_2)_2-X^1-(CH_2)_2-$;

R^3 and R^4, at each occurrence, are independently selected

from:

a) H, aryl, heteroaryl, F, Cl, Br, I, CN, CF_3, NO_2, OH, OR^9, $O(CH_2)_pNR^{11}R^{12}$, $OC(=O)R^9$, $OC(=O)NR^{11}R^{12}$, $O(CH_2)_pOR^{10}$, CH_2OR^{10}, $NR^{11}R^{12}$, $NR^{10}S(=O)_2R^9$, and $NR^{10}C(=O)R^9$;

b) CH_2OR^{14};

c) $NR^{10}C(=O)NR^{11}R^{12}$, CO_2R^{10}, $C(=O)R^9$, $C(=O)NR^{11}R^{12}$, $CH=NOR^{10}$, $CH=NR^{10}$, $(CH_2)_pNR^{11}R^{12}$, $(CH_2)_pNHR^{14}$, and $CH=NNR^{11}R^{12}$;

d) $S(O)_yR^9$, $(CH_2)_pS(O)_yR^9$, $CH_2S(O)_yR^{14}$;

e) alkyl having from 1 to 8 carbons, alkenyl having from 2 to 8 carbons, and alkynyl having 2 to 8 carbons, wherein

1) each alkyl, alkenyl, or alkynyl group is unsubstituted; or

2) each alkyl, alkenyl, or alkynyl group is substituted with 1 to 3 R^5;

R^5 is selected from aryl having from 6 to 10 carbons,

heteroaryl, arylalkoxy, heterocycloalkoxy, hydroxyalkoxy, alkyloxy-alkoxy, hydroxyalkylthio, alkoxy-alkylthio, F, Cl, Br, I, CN, NO_2, OH, OR^9,

$X^2(CH_2)_pNR^{11}R^{12}$, $X^2(CH_2)_pC(=O)NR^{11}R^{12}$, $X^2(CH_2)_pOC(=O)NR^{11}R^{12}$, $X^2(CH_2)_pCO_2R^9$, $X^2(CH_2)_pS(O)_yR^9$, $X^2(CH_2)_pNR^{10}C(=O)NR^{11}R^{12}$, $OC(=O)R^9$, $OC(=O)NHR^{10}$, O-tetrahydropyranyl, $NR^{11}R^{12}$, $NR^{10}C(=O)R^9$, $NR^{10}CO_2R^9$, $NR^{10}C(=O)NR^{11}R^{12}$, $NHC(=NH)NH_2$, $NR^{10}S(O)_2R^9$, $S(O)_yR^9$, CO_2R^{10}, $C(=O)NR^{11}R^{12}$, $C(=O)R^9$, CH_2OR^{10}, $CH=NNR^{11}R^{12}$, $CH=NOR^{10}$, $CH=NR^9$, $CH=NNHCH(N=NH)NH_2$, $S(=O)_2NR^{11}R^{12}$, $P(=O)(OR^{10})_2$, OR^{14}, and a monosaccharide having from 5 to 7 carbons wherein each hydroxyl group of the monosaccharide is independently either unsubstituted or is replaced by H, alkyl having from 1 to 4 carbons, alkylcarbonyloxy having from 2 to 5 carbons, or alkoxy having from of 1 to 4 carbons;

X^2 is O, S, or NR^{10};

Q is selected from:

1) NR^6;

2) an unsubstituted alkylene of 1-3 carbons;

3) a substituted alkylene of 1-3 carbons;

4) $CH=CH$, $CH(OH)CH(OH)$, O, S, $S(=O)$, $S(=O)_2$, $C(=O)$, $C(=NOR^{11})$, $C(OR^{11})(R^{11})$, $C(=O)CH(R^{13})$, $CH(R^{13})C(=O)$, $C(R^{10})_2$, $C(=NOR^{11})CH(R^{13})$, $CH(R^{13})C(=NOR^{11})$, CH_2Z, $Z\text{-}CH_2$, CH_2ZCH_2;

Z is selected from $C(R^{11})(OR^{11})$, O, S, $C(=O)$, $C(=NOR^{11})$, and NR^{11};

R^6 is selected from H, SO_2R^{2a}, CO_2R^{2a}, $C(=O)R^{2a}$, $C(=O)NR^{1c}R^{1d}$, and alkyl of 1-8 carbons, alkenyl of 2-8 carbons, alkynyl of 2-8 carbons, wherein:

1) each alkyl, alkenyl, and alkynyl is unsubstituted;

2) each alkyl, alkenyl, and alkynyl is substituted with 1-3 R^5; or

alternatively, when Q is NR^6 or $C(R^{10})_2$, R^6 or one R^{10} joins with R^2 to form:

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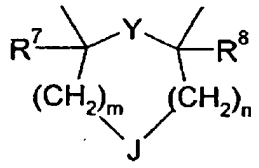


wherein R^7 and R^8 are each independently selected from H, OH, alkyl having from 1 to 6 carbons, alkoxy having from 1 to 6 carbons, substituted or unsubstituted arylalkyl having from 6 to 10 carbons, substituted or unsubstituted heteroarylalkyl, $(CH_2)_pOR^{10}$, $(CH_2)_pOC(=O)NR^{11}R^{12}$, and $(CH_2)_pNR^{11}R^{12}$; or

R^7 and R^8 together form a linking group of the formula

CH_2-X^3-CH_2;

X^3 is a bond, O, S, or NR^{10};

R^9 is selected from alkyl having 1 to 6 carbons, $(CH_2)_r$aryl and $(CH_2)_r$heteroaryl;

R^{10} is selected from H, alkyl having from 1 to 6 carbons, $(CH_2)_r$aryl and $(CH_2)_r$heteroaryl;

R^{11} and R^{12}, at each occurrence, are independently selected from:

1) H and substituted or unsubstituted alkyl having from 1 to 6 carbons; or

2) R^{11} and R^{12} together form -$(CH_2)_2$-X^1-$(CH_2)_2$-;

Y is selected from O, S, $N(R^{10})$, $N^+(O^-)(R^{10})$, $N(OR^{10})$, and CH_2;

J is selected from the group consisting of a bond, O, CH=CH, S, C(=O), $CH(OR^{10})$, $N(R^{10})$, $N(OR^{10})$, $CH(NR^{11}R^{12})$, $C(=O)N(R^{17})$, $N(R^{17})C(=O)$, $N(S(O)_yR^9)$, $N(S(O)_yNR^{11}R^{12})$, $N(C(=O)R^{17})$, $C(R^{15}R^{16})$, $N^+(O^-)(R^{10})$, CH(OH)CH(OH), and $CH(O(C=O)R^9)CH(OC(=O)R^9)$;

R^{13} is selected from alkyl having from 1 to 4 carbons, aryl, and arylalkyl having from 7 to 14 carbons;

R^{14} is the residue of an amino acid after the hydroxyl group of the carboxyl group is removed;

R^{15} and R^{16}, at each occurrence is selected from H, OH,

$C(=O)R^{10}$, $O(C=O)R^{9}$, alkyl-OH, and CO_2R^{10};

R^{17} is selected from the group consisting of H, alkyl, aryl, and heteroaryl;

m and n are independently selected from 0, 1, and 2;

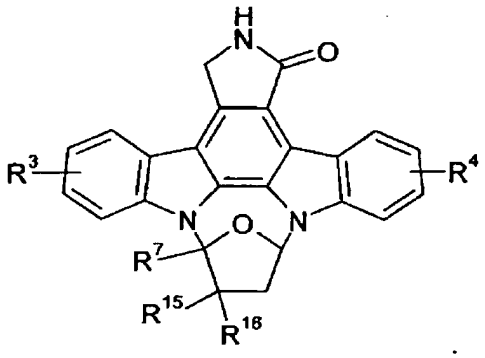
p is independently selected from 1, 2, 3, and 4;

r is independently selected from 0, 1, and 2; and

y is independently selected from 0, 1 and 2.

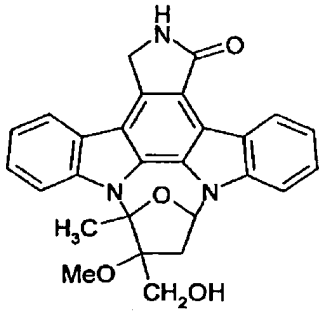
32. (Withdrawn) The method of claim 31 wherein ring B and ring F of the fused pyrrolocarbazole are phenyl, G-X-W is selected from $CH_2NR^1C(=O)$, $C(=O)NR^1CH_2$, and $C(=O)NR^1C(=O)$, and Q is NR^6.

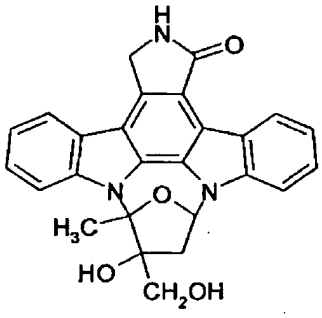
33. (Withdrawn) The method of claim 32 wherein the fused pyrrolocarbazole has the formula:



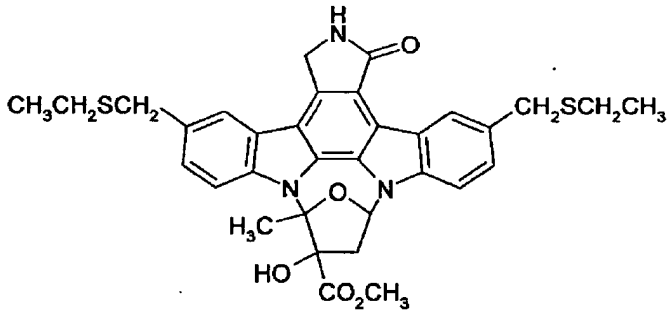
34. (Withdrawn) The method of claim 33 wherein R^3 and R^4 of the fused pyrrolocarbazole are selected from H, alkyl, Cl, Br, CH_2OH, $CH_2SOCH_2CH_3$, $CH_2SO_2CH_2CH_3$, $NHCONHC_6H_5$, $CH_2SCH_2CH_3$, $CH_2SC_6H_5$, $NHCO_2CH_3$, $CH_2OC(=O)NHCH_2CH_3$, $N(CH_3)_2$, CH=NNH, $CH_2N(CH_3)_2$, and $CH_2OCH_2CH_3$; R^7 is selected from H and alkyl; and R^{15} and R^{16} are independently selected from H, alkyl, OH, CH_2OH, alkoxy, and CO_2alkyl.

35. (Withdrawn) The method of claim 34 wherein the fused pyrrolocarbazole has the formula:





or



36. (Withdrawn) The method of claim 27 wherein the organic solvent is at least one polyethylene glycol has a molecular weight from about 300 to 8000 Daltons.

37. (Withdrawn) The method of claim 36 wherein the polyethylene glycol has a molecular weight from about 400 to 1500 Daltons.

38. (Withdrawn) The method of claim 37 wherein the polyethylene glycol is selected from PEG-400, PEG-600, PEG-1000, and PEG-1450.

39. (Withdrawn) The method of claim 27 wherein the surfactant is selected from a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of polyethylene glycol, a hydroxylated

lecithin, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, a poloxyl stearate, a poloxyl castor oil, and polyethylene glycol hydroxy stearate.

40. (Withdrawn) The method of claim 39 wherein the surfactant is selected from a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of polyethylene glycol, a hydroxylated lecithin, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, a poloxyl stearate, a poloxyl castor oil, and polyethylene glycol hydroxy stearate.

41. (Withdrawn) The method of claim 40 wherein the surfactant is a polyoxyl stearate.

42. (Withdrawn) The method of claim 28 wherein the antioxidant is selected from ascorbic acid, a fatty acid ester of ascorbic acid, butylated hydroxytoluene, propyl gallate, and butylated hydroxyanisole.

43. (Withdrawn) The method of claim 42 wherein the antioxidant is a mixture of butylated hydroxyanisole, propyl gallate and citric acid.

44. (Withdrawn) The method of claim 27 wherein the organic solvent is a polyethylene glycol with a molecular weight from about 400 to 1500 Daltons and the surfactant is a polyoxyl stearate.

45. (Withdrawn) The method of claim 44 wherein the polyethylene glycol is PEG-400, PEG-600, PEG-1000, or PEG-1450 and the polyoxyl stearate is Myrj® 52.

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46. (Withdrawn) The method of claim 27 wherein the organic solvent is a polyethylene glycol mixture selected from PEG-400/PEG-1000, PEG-400/PEG-1450, PEG-600/PEG-1000, or PEG-600/PEG-1450 and the polyoxyl stearate is Myrj® 52.